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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,906	03/23/2004	Jonathan J. Langberg	PVI-5813CIP1CON2	2408

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EDWARDS LIFESCIENCES CORPORATION
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EXAMINER

SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
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3774

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04/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/806,906	Applicant(s) LANGBERG ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 12, 19, 21-23, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Diederich et al. (US Pat. No. 6,117,101). Diederich et al. discloses the following of the claimed invention: a method of remodeling a mitral valve annulus to reduce mitral valve regurgitation, comprising the steps of: advancing an adjustable prosthesis (100) with a catheter (130) in a first configuration to a position adjacent the mitral valve annulus (Fig. 3; col. 15, lines 42-58); manipulating the prosthesis from the first configuration toward a second configuration that exerts a compressive force against the mitral valve annulus with a forming element (175) (Fig. 4; col. 16, lines 31-56); and monitoring and assessing hemodynamic function to adjust the prosthesis to a third configuration or maintain its current configuration (col. 19, lines 54 through col. 20, lines 8). The venous system is percutaneously accessed using a femoral vein (col. 14, lines 23- 38; col. 16, lines 31-40). A kit of various sizes of the prosthetics is provided so that after measuring, the appropriate size prosthesis may be selected (col. 21, lines 5-23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-11 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Wright (US Pat. No. 5,522,884). Diederich et al. teaches the invention substantially as claimed, but Diederich et al. does not teach locking the prosthesis in a certain configuration. Wright teaches mitral annuloplasty rings where the rings are held in place by the various means claimed by the Applicant in col. 1, line 40 through col. 3, line 53 for the purpose of affixing the necessary parts of the prosthesis in their appropriate positions. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to modify the device of Diederich et al. by using locking means in order to affix the necessary parts of the prosthesis in their appropriate positions.

Claims 13 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Grimes (US Pat. No. 6,312,447). Diederich et al. teaches the invention substantially as claimed, but Diederich et al. does not teach using transesophageal echo cardiography to monitor the patient's hemodynamic function. Grimes teaches methods of mitral valve repair that uses transesophageal echo cardiography in column 4 for the purpose of ensuring the device are in their proper locations. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use transesophageal echo cardiography in order to ensure the devices are in their proper positions.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Purdy et al. (US Pat. No. 5,562,729). Diederich et al. teaches the invention substantially as claimed, but Diederich et al. does not teach the level of regurgitation achieved by the device.

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Purdy et al. teaches valve repair that minimizes heart valve regurgitation in col. 12, lines 17-37 for the purpose of improving blood flow. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use the device of Diederich et al. to achieve at least a one grade reduction in regurgitation in order to improve blood flow.

Claims 14 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Fowler, Jr. et al. (US Pat. No. 5,086,776). Diederich et al. teaches the invention substantially as claimed, but Diederich et al. does not teach using surface echo cardiography to monitor the patient's hemodynamic function. Fowler, Jr. et al. teaches methods of monitoring heart performance using surface echo cardiography in col. 1, lines 10-25 to utilize its noninvasive properties. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use surface echo cardiography in order to utilize its noninvasive properties.

Claims 15 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Killman (US Pat. No. 5,846,198). Diederich et al. teaches the invention substantially as claimed, but Diederich et al. does not teach using intracardiac echo cardiography. Killman teaches heart monitoring means including intracardiac echo cardiography in col. 2, line 55 through col. 3, line 2 for the purpose of utilizing the procedure's improved imaging. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use intracardiac echo cardiography in order to improve imaging of the procedure.

Claims 16 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Mehta (US Pat. No. 5,476,453). Diederich et al. teaches the invention

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substantially as claimed, but Diederich et al. does not teach using fluoroscopy with radiocontrast media. Mehta teaches methods of coronary repair using fluoroscopy with radiocontrast media in col. 1, lines 34-67 for the purpose of utilizing its visual guiding capabilities. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use fluoroscopy with radiocontrast media in order to utilize its visual guiding capabilities.

Claims 17 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of McIntyre (US Pat. No. 5,291,895). Diederich et al. teaches the invention substantially as claimed, but Diederich et al. does not teach using wedge pressure measurements to monitor hemodynamic function. McIntyre teaches methods of evaluating heart mechanical performance using wedge pressure measurements to monitor hemodynamic function in col. 15, line 61 through col. 16, line 15 for the purpose of utilizing its noninvasive properties. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use wedge pressure measurements to monitor hemodynamic function in order to utilize its noninvasive properties.

Claims 18, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Kadhiresan (US Pat. No. 5,935,081). Diederich et al. teaches the invention substantially as claimed, but Diederich et al. does not teach using an ongoing drug therapy. Kadhiresan teaches long-term heart monitoring procedures using an ongoing drug therapy in col. 4, lines 8-46 for the purpose of improving the patients' quality of life. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use an ongoing drug therapy in order to improve the patients' quality of life.

Response to Arguments

Applicant's arguments filed 1/28/2009 have been fully considered but they are not persuasive. The Applicant contends that the Diederich reference does not disclose its device exerting a compressive force on the mitral valve annulus. The examiner respectfully disagrees. Diederich et al. states that its device may be used in a variety of procedures affecting different areas of the heart. The device may be used on the left atrium and the mitral valve as described in col. 14, lines 23-65. The Applicant further contends that the Diederich reference does not disclose assessing mitral valve regurgitation. However, the Diederich et al. reference describes monitoring conduction, temperature, and blood flow through the location of the device (please see col. 19, line 34-col.20, line 8; col. 37, 50-col. 38, line 25). As the device may be located within mitral valve and the left atrium the blood flow and therefore, the regurgitation levels, through these areas will be monitored as well.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./

Examiner, Art Unit 3774

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774